MSN Life Sciences Private Limited

NEW PRODUCTS VALIDATION STATUS (2025-26)

NEW PRODUCTS LIST AT LS-III FOR 2025-2026:

MSN Life Sciences Private Limited

1. SPARSENTAN (Modified process) - (Completed)
2. LEVODOPA - (Completed)
3. GADOTERIDOL - (Completed)
4. FEZOLINETANT - (Completed)
5. ENSIFENTRINE - (Completed)
6. ZAVAGEPANT - (Completed)
7. CALTERIDOL - (Completed)
8. BENZGALANTAMINE - (Completed)
9. TEGOPRAZAN- (Completed)
10. ACORAMIDIS - Under Progress
11. FOS LEVODOPA - Under Progress
12. OBICETRAPIB HEMICALCIUM – To be started

SPARSENTAN
(Modified Process)

TRAIL & VALIDATION CONSISTANCIES / VARIABILITIES :

MSN Life Sciences Private Limited

SPARSENTAN (SPN): (Modified process)
Total No of Stages: 4
Stage Codes: SPAN1, SPAN2, SPAN3 & SPAN4
DMF stages: 04
No observations stages : 02
Issues observed in below stages: 02

Stage No.	B.No.	Activity	Observation	Action Proposed	Justification / Reason
SPAN1	SPAN100725 SPAN100825 SPAN100925	Validation	No observations were recorded, Validation batches executed as per BPR	NA	NA
SPAN2	SPAN200825 SPAN200925 SPAN201025 SPAN201125 SPAN201225	Validation	No observations were recorded, Validation batches executed as per BPR	NA	NA

TRAIL & VALIDATION CONSISTANCIES / VARIABILITIES :

MSN Life Sciences Private Limited

SPARSENTAN (SPN): (Modified process)
Total No of Stages: 4
Stage Codes: SPAN1, SPAN2, SPAN3 & SPAN4
DMF stages: 04
No observations stages : 02
Issues observed in below stages: 02

Stage No.	B.No.	Activity	Observation	Action Proposed	Justification / Reason
SPAN3	SPNA301025 SPNA301125	Validation	1) Purge the Reaction mass with M-064, but reaction mass addition into Ethanolic HCL solution.	1) Ethanolic HCL solution prepared with Assay in between 10% to 20% and reaction mass added into Ethanolic HCL solution	To control the impurity (Isomer Impurity, dimer impurity and after dimer one more impurity observed)
	SPNA301225 SPNA301325	Validation	2) Purge the Reaction mass with M-064, but reaction mass addition into Ethanolic HCL solution. 3) Molecular sieves not a part of the raw material, but used in this batches.	2) Ethanolic HCL solution prepared with Assay in between 10% to 20% and reaction mass added into Ethanolic HCL solution 3) Molecular sieves two lots used (30Kg+30Kg)	To control the impurity (Isomer Impurity, dimer impurity and after dimer one more impurity observed).
	Note: Addendum process executed for commercial batches (Which was developed in DMF, MTBE process)				

TRAIL & VALIDATION CONSISTANCIES / VARIABILITIES :

MSN Life Sciences Private Limited

SPARSENTAN (SPN): (Modified process)
Total No of Stages: 4
Stage Codes: SPAN1, SPAN2, SPAN3 & SPAN4
DMF stages: 04
No observations stages : 02
Issues observed in below stages: 02

Stage No.	B.No.	Activity	Observation	Action Proposed	Justification / Reason
SPAN32C (2nd Crop)	SPAN32C00425	Validation	1) Crude MLs Material was not isolated (this material Considered as "C") 2) Tech P3 MLs, & API MLs only taken as input for second crop process	Material adjusted with previous batches.	1) Material not isolated and discarded. 2) Due to the Crude and P1 less purity and more impurities.
	SPAN32C00525	Validation	Crude Material ('C') diverted to previous batch (SPAN32C00425).	Unofficially 13.00Kg batch were manufactured for material makeup.	Material adjusted

TRAIL & VALIDATION CONSISTANCIES / VARIABILITIES :

MSN Life Sciences Private Limited

SPARSENTAN (SPN): (Modified process)
Total No of Stages: 4
Stage Codes: SPAN1, SPAN2, SPAN3 & SPAN4
DMF stages: 04
No observations stages : 02
Issues observed in below stages: 02

Stage No.	B.No.	Activity	Observation	Action Proposed	Justification / Reason
SPAN4	SPAN401225	Validation	1) Adjust the quality of material	1) Two validation (V2 & V3) batches were blended. (Any individual unspecified impurity V2- (0.07% & V3- (0.04%) limit NMT 0.1% After blending results 0.05%	To meet the market requirement Material dispatch to M/s Watson pharma customer.
	SPAN401425	Validation	2) Batch charged first and after BPR written	Molecular sieves were used in the n-1 Mfg. process (60.00Kg), hence batch quality monitored.	Batch quality evaluated

LEVODOPA

TRAIL & VALIDATION CONSISTANCIES / VARIABILITIES :

MSN Life Sciences Private Limited

PRODUCT : LEVODOPA
Total No of Stages: 2
Stage Codes: LDOP1 & LDOP2
DMF stages: 2 (LDOP1 & LDOP2)
No observations stages : Nil
Issues observed in below stages: 02

Stage No.	B.No.	Activity	Observation	Action Proposed	Justification / Reason
LDOP 1	LDOP100125	Pre-validation & Validation	1) Trial batch Executed 2) Validation batches Material received from outsourced.	Documented	Stage-1 Two experimental batches Executed and API material received from R&D
LDOP 2	LDOP200125	Pre-validation & Validation	Material received from outsourced and not manufacturing at LS-III.	Documented	

BENZGALANTAMINE

TRAIL & VALIDATION CONSISTANCIES / VARIABILITIES :

MSN Life Sciences Private Limited

PRODUCT : BENZGALANTAMINE
Total No of Stages: 2
Stage Codes: BNGN1 & BNGN2
DMF stages: 2 (BNGN1 & BNGN2)
No observations stages : 01
Issues observed in below stages: 01

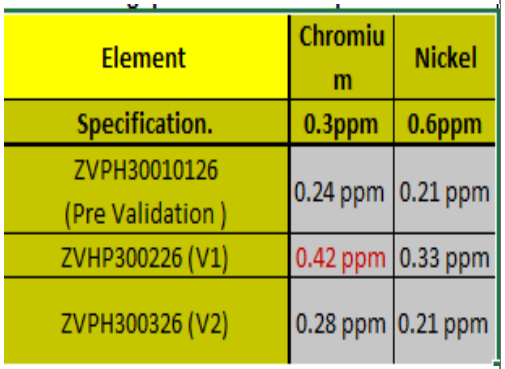
Stage No.	B.No.	Activity	Observation	Action Proposed	Justification / Reason
BNGN 1	NA	Pre-validation & Validation	No observations were recorded, Validation batches executed as per BPR	NA	NA
BNGN 2	BNGN200126	Pre-validation	Lower side yield were observed at Yield finalization operation.	1) 100.0gr material Adjusted and Further Validation yield range changed	Initial scale up batch
	BNGN200426 (V3)	Validation	In complete analysis PXRD test one	validation batch (V3) material replaced with	PXRD issue resolved

ZAVAGEPANT

TRAIL & VALIDATION CONSISTANCIES / VARIABILITIES :

MSN Life Sciences Private Limited

PRODUCT : ZAVAGEPANT
Total No of Stages: 3
Stage Codes: ZVPH1, ZVPH2 & ZVPH3
DMF stages: 3 (ZVPH1, ZVPH2 & ZVPH3)
No observations stages : 02
Issues observed in below stages: 01

Stage No.	B.No.	Activity	Observation	Action Proposed	Justification / Reason
ZVPH 3	ZVPH30010126(Trial)) ZVPH300226(V1) ZVPH300326(V2)	Pre-Validation & Validations	1) Chromium content obtained results for ZVPH300226(V1) is 0.42ppm against the specification limit NMT 0.3ppm Pre-validation and V2 batch exceeding 80% of specification limit. 2) Ni content is above 30% of the specification limit (NMT 0.6ppm)	Under discussion	

Element	Chromium	Nickel
Specification.	0.3ppm	0.6ppm
ZVPH30010126 (Pre Validation)	0.24 ppm	0.21 ppm
ZVHP300226 (V1)	0.42 ppm	0.33 ppm
ZVPH300326 (V2)	0.28 ppm	0.21 ppm

TEGOPRAZAN

TRAIL & VALIDATION CONSISTANCIES / VARIABILITIES :

MSN Life Sciences Private Limited

PRODUCT : TEGOPRAZAN
Total No of Stages: 2
Stage Codes: TEPZ1 & TEPZ2
DMF stages: 2 (TEPZ1 & TEPZ2)
No observations stages : 01
Issues observed in below stages: 01

Stage No.	B.No.	Activity	Observation	Action Proposed	Justification / Reason
TEPZ 1	NA	Pre-validation & Validation	No observations were recorded, Validation batches executed as per BPR	NA	NA
TEPZ 2	TEPZ200126	Pre-validation	In complete analysis PXRD test one unknown peak was observed.	Material re-processed	To meet the quality parameter